LONG BEACH MEMORIAL MEDICAL CENTER

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December 21, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 98N-0581: rule and Proposed Rule: Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents and Requirements for Blood, Components, and Blood Derivatives

To Whom It May Concern:

Long Beach Memorial Medical Center Blood Bank is a hospital based Blood Bank in a 700+ bed community medical center. We collect 3 – 4,000 units of whole blood annually, 25 – 30% of which are autologous units for surgeries at our medical center. Over 10,000 red cell units are transfused annually , with approximately 10% being autologous units.

Long Beach Memorial Medical Center (LBMMC) appreciates the opportunity to comment on the Food and Drug Administration's (FDA) rule and proposed rule on the requirements for testing human blood donors for evidence of infection due to communicable disease agents and requirements for blood, blood components, and blood derivatives. We specifically would like to comment on alternatives to testing each autologous donation for all communicable disease agents listed in proposed 610.40 and the impact the proposal would be expected to have on our operations.

A. While we agree that the goal to "reduce the risk of transmission of communicable disease" is a worthy one, we do not believe testing autologous units will resolve this concern as long as test positive units are retained for use by the autologous donor/patient. A recent memo from the AABb warned all hospitals that denying HIV-infected patients the opportunity to use their own blood may be considered unlawful. LBMMC's ethical position has always supported autologous donations/transfusions for all patients regardless of test postivity status. *We believe that facilities should be allowed to develop and use a defined process and process controls as an alternative to infectious disease testing when collecting, processing and transfusing autologous units at the same facility.* In 1992 we implemented a process we believe offers comparable, if not better, safety as compared to communicable disease testing of autologous units.

Briefly, our process includes:

1. Assignment of a 3 digit code on an armband to each LBMMC autologous donor at the time of collection of autologous units for a potential transfusion episode.

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2. Processing and labeling autologous units separately from allogenic units.
3. Placement of an additional label on the untested autologous units specifying that infectious disease testing is not done.
4. Storage of labeled autologous units segregated from allogenic units.
5. Issuing of autologous units in a plastic bag "locked" with a plastic lock set to the specific patient's 3 digit code.
6. Transfusionist must identify the 3 digit code on the patient's armband in order to "unlock" the bag containing the autologous units.

This process includes visual and physical clues/process controls that identify to all involved in the process that the units being handled are autologous. From 1/97 through 11/31/99, LBMMC collected 3,356 autologous units that were for patients having surgery at our facility. None of these units were subjected to infectious disease marker testing. Of these collected units, 1797 were transfused. No transfusion errors were documented in the 35 months evaluated.

B. Requirements to perform infectious disease marker testing on autologous units can be expected to require development of multiple new processes to handle situations unique to autologous donations/transfusions. Multiple processes with exceptions make it difficult to use one of the best process control theories: the KISS (keep it simple) technique. Examples of new separate processes that would need to be developed include processes to handle:

1. The temporarily quarantine of repeat reactive (RR) autologous units (while awaiting results of confirmatory/supplementary testing) in a manner which allows staff to track and identify the presence and location of these "pending" units.
2. Completion of processing and labeling of a RR unit when its confirmatory/ supplementary test result will not be completed prior to the scheduled date of need of the autologous unit.
3. Completion of processing and labeling of a RR unit with confirmatory testing completed with either confirmed reactive or non-reactive (NR) results.
4. Labeling RR autologous units separately from NR autologous unit and allogenic units.
5. Notification of patient's physician- before and after positive test confirmation and before a second donation by the donor can occur.
6. Notification of autologous donors with positive test results (letters would need to differ from letters to allogenic donors)
7. Deferral registry entries for autologous donors with RR results (process would differ from allogenic in order to allow collection of subsequent autologous unit after an initial donation tested positive).

The extensive procedures to address the above stated processes and the "exception-type" handling which will inevitabley be required for many situations that don't fall into the standard protocols introduce the potential for increased errors and accidents. We believe the overall safety of all our transfusion recipients can be best served if we spend our efforts on the continuing growth and expansion of our quality program and process rather than on development of new processes for handling autologous units.

C. We believe the development of new processes, procedures, computer database changes and staff training will require significantly more than the 16 hours estimate for our type of facility. From experience, we know computer database changes and the subsequent validatations alone require a minimum of 48 hours direct hands-on time. An ongoing time commitment for the special handling of infections disease test positive autologous units, including specimen send-out for confirmatory testing, donor and physician multiple notifications, handling donor deferral files, etc, is estimated at a minimum of 2 hours per donor with RR results.

D. We agree that the use of autologous units for allogenic transfusions should not be permitted.

Once again, LBMMC appreciates the opportunity to comment on the proposed rule. If you have any questions, please feel free to contact either of us at the following address or phone numbers.

Sincerely,

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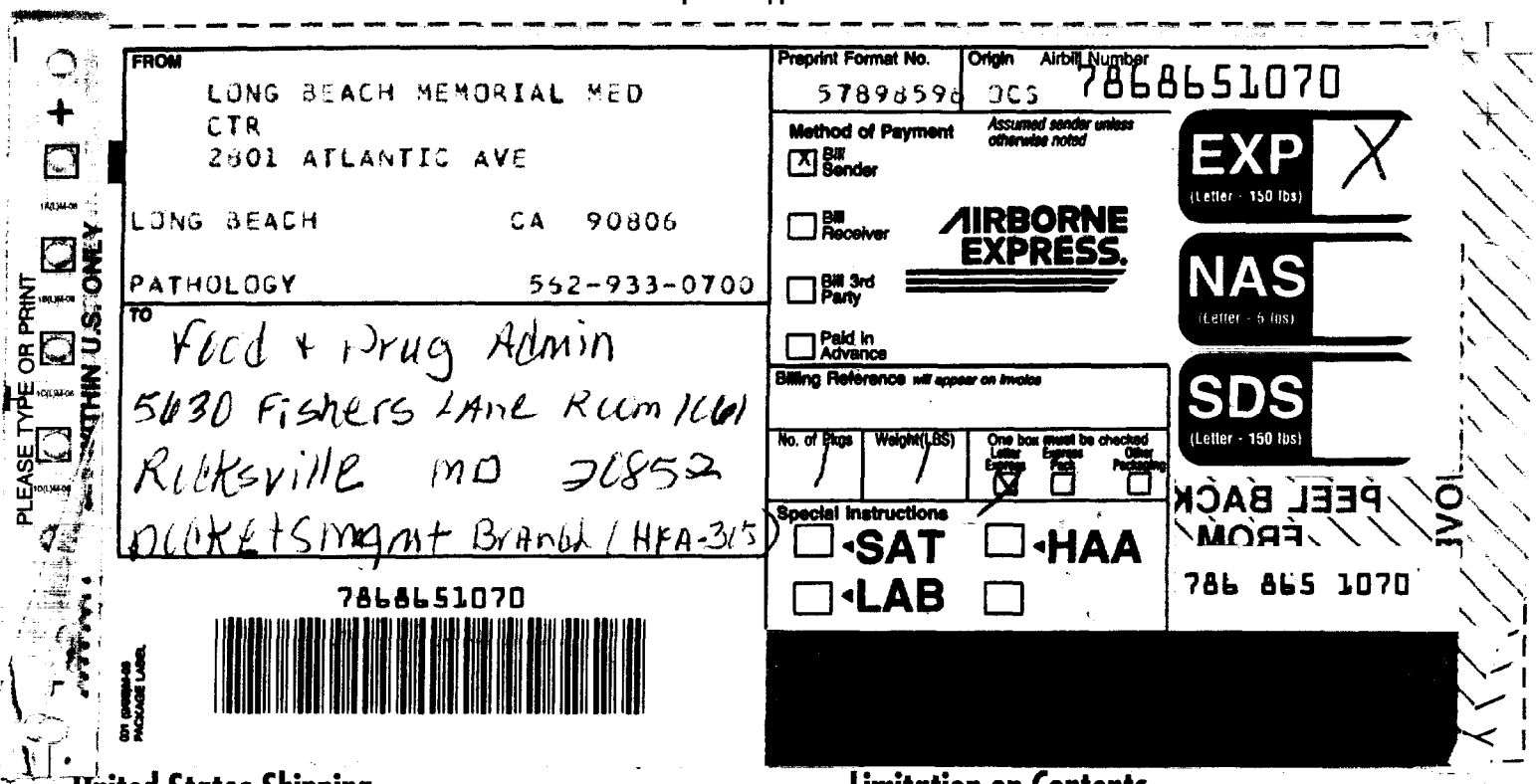

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